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**APPLICATION NUMBER: 60/563,058**

**FILING DATE: April 16, 2004**

**RELATED PCT APPLICATION NUMBER: PCT/US05/12877**



Certified by

*Don W. Dudas*

Under Secretary of Commerce  
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## PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53 (c).

		DOCKET NUMBER	CRD5080PRV
INVENTOR(s) / APPLICANT(s)			
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TITLE OF THE INVENTION (280 characters max)			
Extended Duration Vascular Filter			
CORRESPONDENCE ADDRESS			
Direct all correspondence to:			
<input checked="" type="checkbox"/> Customer Number 000027777			
OR			
<input type="checkbox"/> Firm of Individual Name:			
ENCLOSED APPLICATION PARTS (check all that apply)			
<input checked="" type="checkbox"/> Specification	Number of Pages	3	<input type="checkbox"/> Application Data Sheet
<input type="checkbox"/> Claims	Number of Claims		<input type="checkbox"/> CD(s), Number
<input checked="" type="checkbox"/> Drawing(s)	Number of Sheets	1	<input checked="" type="checkbox"/> Express Mail Transmittal Certificate
EU753010043US			
METHOD OF PAYMENT (check one)			
<input type="checkbox"/> A check or money order is enclosed to cover the Provisional filing fees.		Provisional Filing	
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees and credit any overpayment to Deposit Account No. 10-0750		Fee Amount	\$160.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No☐ Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

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DOCKET NO. CRD5080

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Jason R. Sullivan  
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For: Extended Duration Vascular Filter

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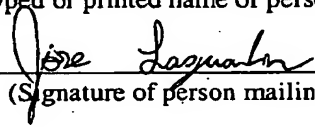
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I hereby certify that this Provisional Application, including three pages and one drawing sheet, with Provisional Application cover sheet, is being deposited with the United Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450

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## **EXTENDED DURATION VASCULAR FILTER**

Provisional Patent Application

### **Description of the Invention:**

Some vascular filters have a double-basket design with a symmetric flower pattern on each end. One of the advantages is that clots can be evenly captured in both baskets and thus prevent occlusion. To increase filter efficiency and resist occlusion, the filter may preferably be designed to capture clot material in each basket with approximately equal distribution.

In some prior filters, a higher percentage of the clots tended to be captured in the caudal basket. This phenomenon may increase the chance of occlusion because of (1) increased physical obstruction as more clot is captured in one basket, (2) decreased flow through the filter due to preferential accumulation of contents and (3) "upstream" flow stagnation that may induce thrombosis in the cranial basket because of the obstruction of the caudal basket.

The present invention eliminates symmetry in flower patterns by reducing the number of segments originating at the caudal collar from six (6) to three (3), then bifurcating these segments to create the six (6) middle straight struts that touch the vessel wall. This configuration retains the longitudinal symmetry that provides for minimal tilting during deployment, while eliminating the symmetry between ends of the filter. As a result, the filtration pattern of the caudal basket is slightly reduced, thereby reducing the clot capturing efficiency of that basket. Consequently, less clot is preferentially captured in the "first" caudal basket and is instead captured in the "second" cranial basket. This optimizes the dual basket design to maintain adequate levels of filtration while reducing all three of the factors noted above as contributing to occlusions. Further, this partial shift in clot capturing from the caudal basket to the cranial basket may also increase the total clot burden tolerance (i.e. total mass of clot captured before occlusion or thrombosis) and increase the successful thrombus lysis rate due to the converging geometry of the cranial basket and its tendency to trap clot in the center of the vessel lumen.

The preferred embodiment shown in the drawings is both retrievable vascular filter and permanent vascular filter. A limiting factor to the duration of retrievability is the extent of intimal ingrowth of the vascular lining over the filters' struts, creating physical entrapment. The geometry of the preferred embodiment shown in the drawings is such that initial entrapment occurs at the transition from the flower patterns to the middle straight struts that touch the vessel wall. This entrapment occurs because the segments (considering a caudal to cranial perspective) comprising the filter (1) converge at this transition point on the caudal end of the filter (confluence) and (2) diverge at this transition point on the cranial end of the

filter (bifurcation). Once tissue has overgrown these confluences and bifurcations, the filter segments are entrapped and cannot be withdrawn from the tissue as easily as prior to this overgrowth.

Theoretically, a bifurcation may be more easily withdrawn from tissue than a confluence because the bifurcation tends to separate the tissue under tension when the filter is pulled in the caudal direction. Alternatively, a confluence tends to pile together the tissue under compression when the filter is pulled in the caudal direction. Thus, for the same amount of tissue ingrowth, the bifurcation may require less force to withdraw from its entrapment than the confluence. Conversely, for the same amount of withdrawal force, the bifurcation may be withdrawn from greater depth of entrapment in tissue than the confluence. This would equate to increased duration of retrievability for a retrievable vascular filter, as the process of intimal ingrowth is time dependent.

The preferred embodiment shown in the drawings eliminates the confluence created at this transition point of the caudal end of the filter because the geometry forms the six (6) middle straight struts from only three (3) segments originating at the caudal collar. Thus, the filter geometry (considering a caudal to cranial perspective) still has only nine (9) bifurcations rather than twelve (12) and only six (6) confluences rather than twelve (12) (not including the point of origination of the segments at the caudal collar and the termination of the segments at the cranial collar). This would serve to decrease the resistance to removal for a given thickness of tissue ingrowth and equate to an increased duration of retrievability.

#### **Features And Advantages:**

This design of the preferred embodiment shown in the drawings is based on the dual-basket construction the successful Cordis OptEase™ filter. The cranial basket remains unchanged. The flower pattern would be removed from the caudal basket by alternately eliminating three (3) of the segments originating at the caudal collar. These three (3) segments would then bifurcate and transition to the middle straight struts. Both modifications open up the caudal basket and allow clots to be more likely trapped in the cranial basket.

The advantages include:

1. Reducing thrombosis/occlusion at the caudal basket by
  - a. Decreasing the quantity of clot captured by the caudal basket.
  - b. Decreasing the amount of implant material that may induce turbulence.
2. Reducing thrombosis/occlusion at the cranial basket by
  - a. Decreasing turbulence induced by clot captured in the caudal basket.
  - b. Opening up the caudal basket and minimizing the "up-stream" stagnation of flow.

3. Increasing preferential capturing of clots in cranial basket where the clots are directed to the center of lumen. This effect could result in the following:
  - a. Reducing the tendency for clots to organize and attach to the vessel wall.
  - b. Increasing the lysis rate due to flow dynamics of centrally captured clot.
  - c. Increasing the likelihood of clot being captured in interior of filter would increase the retrievability of said filter because clot trapped inside a filter is more likely to be retrieved with the filter due to entrapment rather than stripped away from the filter during filter collapse and retrieval.
4. Increasing retrievable period by alterations of the filter geometry by
  - a. Eliminating 3 bifurcations in the caudal flower pattern.
  - b. Eliminating 6 confluences at the transition from the caudal segments to the straight middle segments.
  - c. Increasing the ratio of bifurcations to confluences.

**Modifications:**

1. The prototype depicted consists of three (3) segments originating at the caudal collar which in turn bifurcate into the six (6) middle straight struts. An alternative embodiment could consist of six (6) segments originating at the caudal collar which transition directly into the six (6) middle straight struts.
2. The location of the transition from three (3) struts to six (6) struts can be varied to produce the maximum retrieval period.
3. The edges of the segments at the vertexes of the confluences could be shaped or sharpened to reduce the resistance to removal and thereby increase the retrievability period.
4. Dual hooks could be included with the vascular filter of the present invention to facilitate dual direction retrieval.

**Inventors:**

As currently described in this provisional application, the inventors of the present invention is believed to be as follows:

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